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| 10/083,283 | 02/23/2002 | Laura L. Dugan | 53047/31628 | 4140 |

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/083,283 | DUGAN ET AL. | |
| | Examiner | Art Unit | |
| | Leslie A. Royds | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16,18-30 and 56-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18-30 and 56-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *18 July 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

**Claims 1-16, 18-30 and 56-67 are presented for examination.**

Applicant's Information Disclosure Statement filed July 18, 2005 and Amendment and Declaration from Dr. Laura Dugan under 37 C.F.R. 1.132 filed August 11, 2005 have each been received and entered into the application. Accordingly, the abstract, the specification at line 19 of page 2-line 3 of page 3 and claims 1, 3, 16, 18-20 and 56-57 have each been amended and claims 17, 31-55 and 68-69 have been cancelled.

As reflected by the attached, completed copy of form PTO-1449 (one page total), the Examiner has considered the cited references.

In light of the above amendments and accompanying remarks, the objection to the abstract and the rejection of claims 1-4, 6-15, 19-21, 25, 27, 56-59 and 61-67 under 35 U.S.C. 112, second paragraph, have each been hereby **withdrawn**.

### *Claim Rejection - 35 USC § 112, First Paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 18-30 and 56-67 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for extending the lifespan of mice comprising the administration of $C_3$ tris malonic acid $C_{60}$, does not reasonably provide enablement for extending the lifespan of metazoans or metazoan cells in general which comprises the administration of all

of the claimed $C_{60}$ compounds (e.g., claim 1) or "a superoxide dismutase-mimetic" (claim 16) generally, for the reasons already made of record in the previous Office Action dated January 18, 2005 at pages 2-8.

Enablement of Increased Longevity in Organisms Besides Mice

Applicant states that both the Roth et al. and Kitani et al. references relied upon by the Examiner in the body of the rejection significantly pre-date this Application and that both written statements were made in ignorance of the data disclosed in the instant application filed in 2002 that clearly demonstrates lifespan increases in mice with a non-metallic superoxide dismutase mimetic (see Applicant's remarks at page 10). Applicant further submits that mice are regarded as a valid mammalian model system for demonstrating longevity effects that are expected to carry over to other organisms, relying upon the "Interventions Testing Program" reference by the National Institute of Aging (cited by Applicant on the supplemental IDS submitted with the amendment) for additional support of this conclusion. Applicant notes that there is scientific evidence that the particular treatment disclosed in the instant application will result in lifespan increases in multiple organisms (see Applicant's remarks, top of page 12) and asserts that they have met the enablement requirement with respect to increasing the lifespan of metazoan organisms because the increase in superoxide dismutase activity in a widely accepted mammalian organism model appears to involve a common mechanism associated with other treatments shown to increase longevity in multiple metazoan organisms (see Applicant's remarks, middle of page 13). Applicant further submits that the application provides clear guidance on how to make and administer the compounds of the invention to metazoans

(including humans) and additionally provides evidence of how to administer the compounds of the invention to a standard model metazoan (i.e., mice) and, thus, the reduction to practice of the invention in mice is evidence of an enabling disclosure. Applicant alleges that an individual skilled in the art need only apply routine experimentation to make and use the invention in a variety of metazoan organisms.

Applicant's arguments have been carefully considered, but are not found to be persuasive in finding error in the propriety of the present rejection.

First, Applicant states that both the Roth et al. and Kitani et al. references relied upon by the Examiner in the body of the rejection significantly pre-date this Application and that both written statements were made in ignorance of the data disclosed in the instant application. However, the issue of whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. The state of the prior art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains.

The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working examples in the specification. The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date [*Chiron Corp. v. Genentech Inc.*, 363 F.3d 247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004)]. See MPEP §2164.05(b).

Thus, the state of the art does not take into account what is disclosed in the instant application, but rather is determined by the knowledge and skill in the art at the time of filing of the presently claimed subject matter. Moreover, since Applicant has declared that they are the first to invent such subject matter, it would logically follow that the art would necessarily be unaware of the data that Applicant has presently disclosed and, thus, such information cannot be taken into account when establishing the state of the art.

In response to such a statement, it is further noted that the Roth et al. and Kitani et al. references were relied upon to show the state of the art at the time of filing of the present application in accordance with the MPEP at §2164.05(b), specifically for the purpose of demonstrating that the state of the art with regard to extending lifespan of multicellular organisms was such that no single pharmaceutical or chemical agent has been shown to be reproducibly effective in intervening in the lifespan of animals (see Kitani et al. as cited at page 6 of the previous Office Action) and that caloric restriction was the only intervention recognized in the art to conclusively and reproducibly slow aging and maintain the health and vitality in mammals (see Roth et al. as cited at pages 5-6 of the previous Office Action). In this regard, such teachings were relied upon to conclude that the state of the art of extending lifespan in mammals was sufficiently unpredictable and underdeveloped such that the assertion that the mere administration of a carbon-60 compound would be capable of extending lifespan in **any** known animal that exists in the world would be met with a great deal of skepticism and would require an objective showing of such success, given that one skilled in the art would not have reasonably expected that such an objective could actually be achieved.

Regarding Applicant's submission that mice are regarded as a valid mammalian model system for demonstrating longevity effects that are expected to carry over to other organisms (relying upon the "Interventions Testing Program" reference by the National Institute of Aging cited by Applicant) and further noting that there is scientific evidence that the particular treatment disclosed in the instant application will result in lifespan increases in multiple organisms (see Applicant's remarks, top of page 12), such is not considered to be a sufficient and objective showing to entitle Applicant to claim a process for extending lifespan in any metazoan known in the art. While it is acknowledged that mice are frequently used as a mammalian model system, the demonstration of activity in a mouse model is not reasonably suggestive of activity in any metazoan.

Applicant has provided evidence showing that the state of art at the time of filing was such that it recognized different methods of extending lifespan in mice, rats, *C. elegans*, Drosophila, houseflies, water-fleas, fish and spiders, but fails to provide sufficient evidence or scientific reasoning beyond Applicant's own assertions that the demonstration of activity in such animal models would have been reasonably suggestive of the same or substantially similar activity in any metazoan animal. Notwithstanding that Applicant has recognized an underlying mechanism of action between the presently claimed method and other methods of treatment known in the art to increase longevity in specific types of metazoan organisms, such a finding does not suggest that the activity of the presently claimed agent in mice could even be reasonably extrapolated to other animal models that have undergone longevity testing (i.e., rats, *C. elegans*, Drosophila, houseflies, water-fleas, fish and spiders), let alone ***any*** multicellular animal.

For example, while humans and jellyfish (of the Phylum Cnidaria; see "Animal Diversity Web", cited on form PTO-892) are both considered "metazoans", the activity of an agent in jellyfish would undoubtedly ***not*** be suggestive of the same or substantially similar activity in a human, specifically because of the vast physiological differences between the two organisms. While jellyfish exhibit differentiated tissues, they do not have true organs (see "Animal Diversity Web" at page 1). This is in direct contract to a human, who not only has highly specialized and differentiated tissues, but also has numerous discrete organs and organ systems by which it functions. Such an example is been described to illustrate the variety and disparate nature of all the organisms considered to fall within the genus of "metazoans".

It is in this regard that Applicant is directed to the MPEP at §2164.08. All questions of enablement are evaluated against the claimed subject matter. Concerning the breadth of a claim relevant to enablement, the only relevant concern is whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves the determination of how broad the claim is with respect to the disclosure and the determination of whether one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.

While Applicant has claimed the extension of lifespan in any metazoan, the disclosure merely provides evidence and scientific reasoning to support the efficacy of the claimed treatment in extending the lifespan of mice. The disclosure of one metazoan organism (i.e., mice) is ***not*** considered to be commensurate in scope with what is presently claimed. Regardless of whether Applicant has disclosed a protocol of making and administering the compounds of the

present invention, the issue at hand is whether Applicant has sufficiently enabled the use of such compounds for extending the lifespan of any metazoan, including a human. In the absence of any sound evidence or scientific reasoning as to why the skilled artisan would extrapolate the data provided in the present disclosure directed solely to mice as being reasonably suggestive of having the same activity in any metazoan, and further in light of the state of the art, which, at the time of filing, was unpredictable and unaware of any universal agent or agents capable of extending lifespan, the present disclosure is not determined to be enabling for the treatment of any metazoan.

While it is acknowledged that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP §2164.02), in light of the state of the art, which recognizes the unpredictable nature of extending lifespan, particularly in animals other than mice, rats, *C. elegans*, Drosophila, houseflies, water-fleas, fish and spiders, the Office would require appropriate disclosure to support the contention that the administration of any one of the claim specified fullerene compound could actually extend the lifespan of any metazoan animal, since the present specification fails to enable one of ordinary skill in the art to practice the invention insofar as it reads of the use of any fullerene compound with Applicant's definition (see claim 1, for example) in any metazoan animal.

Moreover, Applicant's assertion that an individual skilled in the art need only apply routine experimentation to make and use the invention in any metazoan organism is not considered persuasive. Given the breadth of what is presently claimed, what is presently disclosed, what is supported by adequate description in the specification and, further, given the breadth and variety of organisms encompassed by the term "metazoan", the skilled artisan would

have no alternative recourse ***but*** undue experimentation in order to determine how the present invention could be used to extend the lifespan of any known metazoan or even if the presently claimed invention would even have efficacy in all of the animals contained within the large and varied genus of "metazoan".

Lastly, Applicant's reliance on the reference entitled "Interventions Testing Program" from the National Institute of Aging (NIA) to support the assertion that mice are the species most likely to provide information that could be translated to humans is flawed. The reference merely teaches that the mouse will be used a model to test a variety of different interventions to extend lifespan and delay disease and dysfunction, but conspicuously lacks any statement or express teaching that mice are the species most likely to provide information regarding such activity that could be translated to humans.

Enablement of $C_{60}$ Derivatives Other Than $C_3$ tris malonic acid $C_{60}$ and Non-Metallic Superoxide Dismutase Mimetics

Applicant has submitted objective evidence in the form of an Affidavit under 37 C.F.R. 1.132 from Dr. Laura Dugan to show enablement for derivatives other than the exemplary $C_3$ tris malonic acid $C_{60}$ compounds at the time of filing. Applicant further submits that enablement of the exemplary non-metallic superoxide dismutase-mimetics "$C_3$", "Penta", "Tetra" and "$C_3$-lite" was demonstrated with respect to chemical activity (superoxide dismutase activity), inhibition of oxidative stress *in vivo* (inhibition of neuronal cell death), and lifespan increases.

Applicant's arguments and declaration made under 37 C.F.R. 1.132 have been carefully considered, but are not found to be persuasive in enabling the entire breadth of fullerene compounds presently claimed.

The content of the declaration of Dr. Laura Dugan under 37 C.F.R. 1.132 has been carefully considered in its entirety. While such evidence is considered to be adequate support for the enablement of the compounds $C_{60}(C(COOH)_2)_n$, where n=1, 2 or 3, as disclosed in Choi et al. (U.S. Patent No. 6,265,443), and the compounds "$C_3$", "Penta" and "$C_3$-lite", it is not considered to be enabling for the compounds "Tetra" or the other $C_{60}$ compounds not specifically named but within the scope of the general formula recited in the present claims (see claim 1, for example).

"Tetra" is not considered enabled by the present disclosure, nor is it enabled by Dr. Dugan's declaration. Dr. Dugan appears to draw a correlation between the activity of "$C_3$" (the compound fully supported by the present disclosure) and the activity of "Penta", "Tetra" and "$C_3$-lite" by stating that since "$C_3$" was shown to have superoxide dismutase (SOD) activity and reduced NMDA receptor toxicity, and "$C_3$", "Penta", "Tetra" and "$C_3$-lite" exhibited SOD activity and "$C_3$", "Penta" and "$C_3$-lite" all exhibited reduced NMDA receptor toxicity, then "$C_3$", "Penta", "Tetra" and "$C_3$-lite" would also have similar lifespan-extending capabilities as "$C_3$" in comparable *in vivo* doses (see Declaration, bottom of page 2).

However, if the compound "$C_3$" is used as a guide in determining which compounds would be reasonably suggested to have the same or substantially similar activity, it would logically follow that any compound expected to exert the same function would necessarily show the same properties. For example, if "$C_3$" is known to have both SOD activity and reduced NMDA receptor toxicity, then any compound expected to demonstrate the same or substantially

similar activity would also be expected to have SOD activity and reduced NMDA receptor toxicity. According to the results and discussion provided in the Declaration, it appears that only the compounds "Penta" and "$C_3$-lite" show both SOD activity and reduced NMDA receptor toxicity. Thus, it would be reasonably concluded that such compounds would behave similarly to the "$C_3$" compound fully enabled by the disclosure. However, because "Tetra" lacks reduced NMDA receptor toxicity, it would not logically follow that such a compound would have the same activity as "$C_3$", since it lacks one of the major properties of "$C_3$", absent any factual evidence to the contrary. For this reason, the compound "Tetra" is not considered enabled.

It is further noted, however, that the present claims are drawn to any fullerene compound represented by the formula presented in, for example, claim 1, wherein C is directly bonded to two adjacent carbons of $C_{60}$ and R is independently selected from –COOH and –H and x is at least 1.

In light of such, there is a fundamental disparity between the breadth of the fullerene compounds actually claimed and those considered to be enabled by the present disclosure and declaration under 37 C.F.R. 1.132. While Applicant has provided sufficient evidence enabling the use of "$C_3$", "Penta" or "$C_3$-lite", the enablement of these three compounds is not considered to be reasonably suggestive of the same or substantially similar activity in the variety of other fullerene compounds that are encompassed by the present claims. Since it has already been determined that one of the fullerene compounds (i.e., "Tetra") is not enabled because it fails to exert the same properties as the "$C_3$" compound fully enabled by the present disclosure, such a determination casts significant doubt as to whether any one or more of the other fullerene compounds presently claimed would also lack the same activity. In light of this, the skilled

artisan would have been skeptical to extrapolate the activity seen in only three compounds as being reasonably suggestive or representative of the entirety of the compounds actually claimed. Thus, the burden of undue experimentation would have been placed on the skilled artisan to determine which compounds exhibited such lifespan extending properties and which did not.

Again, Applicant is directed to the MPEP at §2164.08 for a discussion of providing enablement commensurate in scope with the claims.

With regard to the enablement of non-metallic superoxide dismutase mimetics, the same reasoning applies. The compounds defined by claims 16-30 are identical to those of claims 1-15 and 56-67. Regardless of the function attributed to such compounds (i.e., that they are non-metallic superoxide dismutase mimetics), they do not differ physically or structurally from those defined in claims 1-15 and 56-67, nor do they differ in the reason for administration (i.e., the therapeutic objective of extending lifespan). As a result, and for the same reasons described above, the compounds "$C_3$", "Penta" and "$C_3$-lite" are considered enabled and the compound "Tetra" and the other fullerene compounds within the scope of the formula defined in claim 19 are not considered enabled by the present disclosure or declaration.

For the reasons stated above, and those already made of record in the previous Office Action dated January 18, 2005 at pages 2-8, rejection of claims 1-16, 18-30 and 56-67 as lacking sufficient enablement is deemed proper and is **maintained**.

Applicant is reminded that the specification and declaration are enabling for the treatment of mice using $C_3$ tris malonic acid, "Penta" or "$C_3$-lite" compounds.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16, 18-30 and 56-67 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lei et al. (U.S. Patent No. 6,777,445) and Stedman's Medical Dictionary (25th Edition, 1990) in view of Chiang (U.S. Patent No. 5,648,523), Choi et al. (U.S. Patent No. 6,265,443) and WO 97/46227 ("WO '227", PCT counterpart of Choi et al. '443), each already of record, for the reasons of record set forth in the previous Office Action dated January 18, 2005 at pages 14-17.

Applicant states that there is no suggestion or motivation to combine the references cited by the Examiner, specifically, that one of ordinary skill in the art would not have had any suggestion or motivation to combine references such as Lei et al. and Choi et al., since both

references disclose completely distinct and unrelated uses. Applicant further submits that the references cited by the Examiner do not provide a reasonable expectation that the combination would be successful in increasing the lifespan of an animal, nor does the combination of cited references fail to disclose or suggest the key claim limitation of extending the lifespan of a metazoan or metazoan cells.

In response to Applicant's argument that there is no suggestion to combine the references, it is recognized that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, Lei et al. was cited to teach a method of treating viral or bacterial infections using the disclosed fullerene compounds and Choi et al. was cited to show that carboxyfullerene esters were known to the skilled artisan as pharmaceutically acceptable fullerene derivatives. The rejection set forth in the previous Office Action did not rely upon the combination of Lei et al. and Choi et al. in order to arrive at the presently claimed method. Rather, Choi et al. was merely cited to show that the use of a carboxyfullerene ester would have been a matter well within the purview of the skilled artisan since such esters were known derivatives of carboxyfullerenes and would have been reasonably expected to exert the same or similar effects as carboxyfullerene itself. In this regard, the skilled artisan would have been motivated to combine the references in order to determine what carboxyfullerene compounds could be employed in the method disclosed by Lei et al. while still maintaining the same

pharmacologic effect. In light of the fact that Choi et al. expressly teaches carboxyfullerene esters as pharmaceutically acceptable fullerene derivative that are reasonably expected to exert the same or similar function to that of carboxyfullerene itself, it would have been plainly obvious to the skilled artisan to combine the references for this objective.

In further response thereto, Applicant's argument that one of ordinary skill in the art would not look to Lei et al. to develop a method for prolonging the lifespan of metazoans or metazoan cells since the subject matter of Lei et al. pertains to the treatment of viral and/or bacterial infections is flawed. Despite the fact that Applicant asserts the difference between Lei et al. and the presently claimed subject matter lies in that Lei et al. demonstrates the use of $C_3$ as a treatment for viral and/or bacterial infection of mice and not to increase the lifespan of normal, uninfected mice, it is noted that Applicant has failed to define their invention in terms of only extending the lifespan of normal, uninfected mice. The present disclosure defines the term "lifespan" as "the average expected length of life of a kind of organism or cell in a particular environment" (see Applicant's disclosure at page 16, lines 10-14), which does not equate to the average expected length of life of a normal, uninfected or healthy kind of organism or cell (i.e., free of insult, infection or injury).

In light of such, the Lei et al. reference remains relevant to the patentability of the presently claimed subject matter. While Lei et al. teaches a method of treating viral and/or bacterial infections using fullerene compounds that results in increased survival, such is not considered to differ from the presently claimed subject matter because the mouse infected with a viral and/or bacterial infection is considered to meet Applicant's definition of an "organism or cell in a particular environment", absent any particular description or requirement as to the

"particular environment" intended by Applicant. Thus, Applicant's argument that the present invention is distinguished from the invention of Lei et al. because Lei et al. teaches an animal infected with a viral and/or bacterial infection, while asserting the present claims are drawn to normal animals, is not found to be persuasive.

Moreover, Applicant's arguments that the cited references do not provide a reasonable expectation that the combination would be successful in increasing the lifespan of an animal or that the combination of references fails to disclose or suggest the key claim limitation of extending the lifespan of a metazoan or metazoan cells are also not found to be persuasive. Lei et al. expressly teach that administration of the disclosed fullerene compounds effects increased survival in mice infected with a viral and/or bacterial infection. Applicant's remarks regarding the distinction between survival and lifespan are ambiguous and fail to delineate a difference between the reference and the presently claimed subject matter. Insofar as Applicant has failed to define the term "lifespan" in any further detail other than stating that it is "the average expected length of life of a kind of organism or cell in a particular environment", the mouse of Lei et al. is considered to be an organism in the particular environment of infection, absent any factual evidence to the contrary, and, thus, the reference is considered to expressly disclose the therapeutic objective of increasing lifespan using fullerene compounds, as well as teaching that the disclosed fullerene active agents have efficacy in effecting such an increase in lifespan.

Rejection of claims 1-16, 18-30 and 56-67 remains proper and is **maintained**.

***Double Patenting***

**Obviousness-Type**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1, 4-16, 18-30 and 56-67 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-33 of copending United States Patent Application No. 10/373,425, for the reasons already made of record at pages 17-19 of the previous Office Action dated January 18, 2005.

Applicant has requested that the provisional rejection be held in abeyance until such time as the claims in the instant application are found to be allowable.

Insofar as the present claims have not been found to be allowable for the reasons already set forth above and in the previous Office Action under 35 U.S.C. §112, first paragraph and 35 U.S.C. §103, the double patenting rejection over pending claims 1, 4-16, 18-30 and 56-67 remains proper and is **maintained**.

***Conclusion***

Rejection of claims 1-16, 18-30 and 56-67 is deemed proper.

No claims of the present application are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

September 9, 2005

CHRISTOPHER S. F. LOW
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